

AS

23. (Amended) The combination of Claim 22 wherein said central support member includes a cylindrical skirt depending from said annular flange and encircling the [disk] base plate of said thread collecting means, said skirt including three apertures in registry with said valve support legs for the passage of thread.

In Claim 24, second line: Please change "disk" to --base plate--.

REMARKS

Upon entry of this Amendment, there will be 28 claims in this patent application. Four of these, i.e. Claims 25-28 are new claims. Claim 3 has been amended to include the limitations found in original Claims 1 and 2; the latter claims, however, have not been cancelled from the application. Claim 21 has been amended to include the limitations found in original Claims 18-20; these latter claims, however, have not been cancelled. Amendments have also been made to Claims 4-7, 13, 14, 20, 23 and 24.

Claims 7 and 11 were rejected under 35 USC 112, second paragraph, as being indefinite. The Examiner has pointed out that the word "shaft" in Claim 7, line 2 should be --axle--: Claim 7 has therefore been amended to substitute --axle-- for "shaft". It is believed this amendment obviates the 35 USC 112 rejection of Claims 7 and 11.

Claims 1, 2, 8, 9, 18 and 20 were rejected under 35 USC 102(a) as being anticipated by The American Edwards Laboratories publication ("A-E publication"). The A-E valve holder comprises a lower body piece and an upper body piece. The lower body piece comprises a disk-like platform having three downwardly depending, spaced valve support legs, three upwardly extending

split posts, and a centrally located, upwardly extending projection which is smaller in height than the split posts. Each split post is located on the upper surface of the platform substantially midway between two of the valve support legs. The upper body piece comprises a disk-like platform having an upstanding, hollow, centrally located hub which is internally threaded. The upper body part further includes three slots in which, when the upper piece is placed on top of the lower piece, the split posts are received. Each split post has a detent which prevents the two pieces from coming apart, or from moving more than a predetermined distance with respect to one another, in the assembled holder. In the assembled configuration the bore of the hub of the upper piece is positioned directly over the centrally located, upstanding projection of the lower body piece. Threads attached to the commissure struts of a heart valve stent run through holes drilled in the valve support legs and pass upwardly where they are fastened to the upper body piece. A threaded handle having a non-threaded projection at its tip is used with the A-E valve holder. As the handle is screwed into the threaded hub of the upper body piece, the non-threaded projection at its tip comes into contact with the centrally located upstanding projection on the lower body piece. Further turning of the handle forces the lower body piece, whose support legs are in contact with the sewing cushion of the stented valve, away from the upper body piece. As indicated by the Examiner at the bottom of page 3 of the Office Action, this increases the tension on the several threads going to the commissure struts and results in the desired inward deflection of the commissures.

All of the Applicants' rejected Claims 1, 2, 8, 9, 18 and 20 require that the valve holder include thread collecting means which function to accumulate a portion of each of the

threads in order to deflect the commissures. The A-E publication does not disclose or suggest a valve holder having the thread collecting means recited in Applicants' claims. In the A-E device, the vertical separation of the upper and lower body pieces applies tension to the threads and thus deflects the commissures; there is, however, no collection of portions of the threads as there is in Applicants' device. It is therefore respectfully contended that the valve holder called for by Applicants' Claims 1, 2, 8, 9, 18 and 20 are patentably distinct from the device shown by the A-E publication and such claims should be allowed.

Applicants' Claim 9 is further allowable by reason of the fact it calls for thread guiding and attaching means which comprise an angled slot in the distal end of each valve support leg. It is respectfully submitted that the valve support legs of the A-E device do not include an angled slot such as that identified by numeral 26 in Applicants' Fig. 3.

Claim 19, which depends from Claim 18, was rejected under 35 USC 103 as being unpatentable over the A-E publication in view of Carpentier et al. It is believed that Claim 19 is allowable for the same reasons given above in support of the patentability of Claim 18.

Claims 3-7, 10, 11 and 21-24 were objected to as being dependent upon a rejected base claim. It was indicated these claims would be allowable if Claims 3 and 21 were rewritten in independent form and further providing, with respect to Claims 7 and 11, that these two claims be suitably amended to overcome the aforementioned 35 USC 112 rejection.

As indicated earlier herein, Claims 7 and 11 have been amended so as to obviate the 112 rejection.

Claim 3 has been amended to include all the limitations found in base Claim 1 and dependent Claim 2. It is believed Claim 3 as amended and dependent Claims 4, 5, 6, 7 and 11 are now in condition to be allowed.

Claim 21 has been amended to include all the limitations found in base Claim 18 and dependent Claims 19 and 20. It is believed that Claim 21 as amended and Claims 22-24 are now in condition to be allowed.

Claims 4, 5, 6, 13, 14, 22, 23 and 24 have been amended by substituting the words --base plate-- for the word "disk". Applicants believe --base plate-- is the proper term to be used in these claims in view of the fact that the first new paragraph of page 7 of the specification, referring to Figs. 4 and 5, states that "thread collecting means 20...consists of a base plate 27 having stub axle 28 extending from one side thereof" (emphasis supplied).

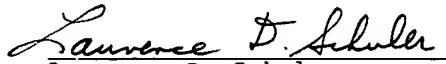
New Claim 25 is similar to, but somewhat narrower in scope than, Claim 1 while new Claim 28 is similar to, but somewhat narrower in scope than, Claim 18. Both new claims include the feature that the thread collecting means be rotatably mounted with respect to said central support member. This feature is not shown or suggested by the A-E publication. It is believed that new Claims 25 and 28, and dependent Claims 26 and 27 are in allowable form and allowance of these claims is respectfully requested.

The allowance of Claims 12-17 is noted. It is respectfully submitted that the amendments made herein to Claims 13 and 14 will have no impact on their allowability.

The Hancock '823 patent was cited to show a heart valve stent having either a natural or synthetic heart valve mounted thereon. This reference neither shows nor suggests the invention claimed by Applicants herein.

In view of the foregoing reasoning and discussion, it is believed that Claims 1-28 define over the references of record and are patentably distinct therefrom. Allowance of these claims is respectfully solicited. If the Examiner believes an interview will expedite the disposition of this patent application, he is requested to call the undersigned attorney collect at Area Code 201, phone 524-5592.

Respectfully submitted,



Lawrence D. Schuler

Reg. No. 26,334

Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(201) 524-5592
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